IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELA PHARMA SCIENCES, LLC, Plaintiff, v. ETON PHARMACEUTICALS, INC., Defendant.	Civil Action No.: _____ **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff Exela Pharma Sciences, LLC ("Plaintiff" or "Exela") by its attorneys, hereby alleges as follows:

NATURE OF ACTION

1. This is an action for infringement of U.S. Patent No. 10,478,453 ("the '453 patent") and U.S. Patent No. 10,583,155 ("the '155 patent") under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including §§ 271(e)(2), 271(a)-(c), and for a declaratory judgment of infringement of the '453 and '155 patents under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. §§ 271(a)-(c). Plaintiff institutes this action to enforce its patent rights covering its FDA-approved ELCYS® brand L-cysteine hydrochloride injection.

THE PARTIES

2. Plaintiff Exela Pharma Sciences, LLC ("Exela") is a company existing under the laws of the state of Delaware and having a principal place of business at 1245 Blowing Rock Blvd., Lenoir, NC 28645.

3. On information and belief, Defendant Eton Pharmaceuticals, Inc. ("Eton") is a corporation organized and existing under the law of the State of Delaware, having a principal place of business at 21925 West Field Parkway, Suite 235, Deer Park, IL 60010.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a) because the action concerns a federal question arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

5. This Court has personal jurisdiction over Eton Pharmaceuticals, Inc. because it is incorporated in Delaware and thus is present in and resides in this District, and because Eton is doing business in this District and thus has purposefully availed itself to the privileges of conducting business in Delaware. On information and belief, Cogency Global Inc., 850 New Burton Road, Suite 201, Dover, Delaware, is Eton's registered agent in Delaware and is authorized to accept service on Eton's behalf.

6. Venue is proper in this District pursuant to 28 U.S.C. § 1400(b) and § 1391 because Eton Pharmaceuticals, Inc. is incorporated in Delaware and thus resides in this District.

FACTUAL BACKGROUND

A. The Development and FDA Approval of Exela's ELCYS® L-Cysteine Product

7. Exela is a relatively small but fast-growing specialty pharmaceutical company focused on developing, manufacturing, and marketing injectable products.

8. L-cysteine is an amino acid that is important for human life. While healthy adults can naturally synthesize small amounts, high-risk patients such as preterm and/or low birth weight infants and patients with severe liver disease require L-cysteine supplementation by parenteral administration (i.e., injection or intravenous infusion). For these patients, L-cysteine is administered as a component of a nutritional supplement regimen referred to as "total parenteral nutrition" (TPN).

9. At the time Exela began developing its L-cysteine product, there was no FDA-approved intravenous L-cysteine hydrochloride product on the market in the United States. However, multiple unapproved and compounded L-cysteine products were on the market during that time that were used in TPN regimens. One significant drawback of such L-cysteine products is that they were known to contain high amounts of aluminum, labeled as containing up to 5,000 mcg/L.

10. TPN admixtures even without L-cysteine were also known to contain high amounts of aluminum, and aluminum toxicity from their use had been reported. Aluminum toxicity can cause serious health problems including dementia, impaired neurologic development, Alzheimer's disease, metabolic bone disease (including impaired bone growth, growth failure, bone pain, muscle weakness, nonhealing fractures, and premature osteoporosis), encephalopathy, and cholestasis (liver disease), among others.

11. In 2000, FDA issued regulations requiring manufacturers to reduce aluminum levels of parenteral products. 65 Fed. Reg. 4103 (Jan. 26, 2000). That regulation became final in 2004. 68 Fed. Reg. 32,979 (June 3, 2003). It requires manufacturers of TPN components to include the following warning on their product labeling: "Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of

aluminum at greater than 4 to 5 [micro]g/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity." 65 Fed. Reg. 4103, 4111 (Jan. 26, 2000). These regulations are codified at 21 C.F.R. § 201.323.

12. In April of 2019, after extensive effort, research, and development, including substantial work to achieve the ≤ 145 mcg/L aluminum level FDA mandated for the product, [Ex. A (8/4/2017 FDA Letter)], Exela secured the first FDA approval for an injectable L-cysteine hydrochloride product containing low aluminum levels, finally fulfilling a long-felt need for such a low-aluminum injectable cysteine product.

13. Exela is the holder of approved New Drug Application ("NDA") No. 210660 for cysteine hydrochloride injection, sold under the brand name ELCYS®.

14. Exela's ELCYS® product is labeled to contain no more than 120 micrograms/liter ("mcg/L," "µg/L" or, more commonly, parts per billion or ppb) of aluminum, and is the only FDA approved L-cysteine product available on the market today. [Ex. B (ELCYS® Label), § 11.]

15. Exela's ELCYS® product "is a sterile, nonpyrogenic solution for intravenous use. Each 10 mL of ELCYS contains 500 mg of cysteine hydrochloride, USP (equivalent of 345 mg of cysteine) in water for injection." [*Id.* at § 11.]

16. The FDA approved ELCYS® with a specification limiting the total impurities in the product, including pyruvic acid and cystine, both of which are observed as degradation products of L-cysteine, to no more than 2.0%.

17. The FDA-approved labeling for Exela's ELCYS® product instructs healthcare providers that "ELCYS is indicated for use as an additive to amino acid solutions to meet the nutritional requirements of newborn infants requiring total parenteral nutrition (TPN) and of

adult and pediatric patients with severe liver disease who may have impaired enzymatic processes and require TPN. It can also be added to amino acid solutions to provide a more complete profile of amino acids for protein synthesis." [*Id.* at § 1.]

18. The FDA-approved labeling for ELCYS® further instructs healthcare providers that "ELCYS is for *admixing use* only. It is *not for direct intravenous infusion*. Prior to administration, ELCYS *must be diluted and used as an admixture* in parenteral nutrition (PN) solutions. The resulting solution is for intravenous infusion into a central or peripheral vein." [*Id.* at § 2.1 (emphases in original).] It goes on to provide instructions for healthcare providers on how to prepare the admixture by following the steps laid out on the label and how to administer PN solutions containing ELCYS®. [*Id.* at §§ 2.2-2.5.]

19. The FDA-approved labeling for ELCYS® instructs that "[t]he dosage of the final PN solution containing ELCYS must be based on the concentrations of all components in the solution and the recommended nutritional requirements *[see Dosage and Administration (2.5)]*." [*Id.* § 2.4.]

20. The FDA-approved labeling for ELCYS® includes the following warnings related to the level of aluminum patients receive: "Aluminum may reach toxic levels with prolonged parenteral administration in patients with renal impairment. Preterm infants are particularly at risk for aluminum toxicity because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which also contain aluminum. Patients with renal impairment, including preterm infants, who receive greater than 4 to 5 mcg/kg/day of parenteral aluminum can accumulate aluminum to levels associated with central nervous system and bone toxicity." [*Id.* at § 5.7.] It further instructs, "[e]xposure to aluminum from ELCYS is not more than 0.21 mcg/kg/day when preterm and term infants less than 1 month of age are administered the

recommended maximum dosage of ELCYS (15 mg cysteine/g of amino acids and 4 g of amino acids/kg/day) *[see Table 1, Dosage and Administration (2.5)]*. When prescribing ELCYS for use in PN containing other small volume parenteral products, the total daily patient exposure to aluminum from the admixture should be considered and maintained at no more than 5 mcg/kg/day *[see Use in Specific Populations (8.4)]*." [*Id.*]

B. The Asserted '453 Patent

21. On November 19, 2019, the United States Patent and Trademark Office ("USPTO") issued the '453 patent, entitled "Stable, Highly Pure L-Cysteine Compositions for Injection and Methods of Use," and naming John Maloney, Aruna Koganti, and Phanesh Koneru as inventors. A copy of the '453 patent is attached to this Complaint as Exhibit C.

22. The '453 patent is assigned to Plaintiff Exela.

23. On November 19, 2019, Exela submitted the '453 patent for listing in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book," which provides notice concerning patents covering FDA-approved drugs.

24. On or about November 20, 2019, the FDA published the '453 patent in the Orange Book.

25. Claim 1 of the '453 patent reads as follows:

> A stable L-cysteine composition for parenteral administration, comprising:
> L-cysteine or a pharmaceutically acceptable salt thereof and/or hydrate thereof in an amount from about 10 mg/mL to about 100 mg/mL;
> Aluminum (Al) in an amount from about 1.0 parts per billion (ppb) to about 250 ppb;
> L-cystine in an amount from about 0.001 wt % to about 2.0 wt % relative to L-cysteine;
> pyruvic acid in an amount from about 0.001 wt % to about 2.0 wt % relative to L-cysteine;
> a pharmaceutically acceptable carrier, comprising water;
> headspace oxygen that is from about 0.5% v/v to 4.0% v/v from the time of manufacture to about 1 month from manufacture when stored at room temperature;

dissolved oxygen present in the carrier in an amount from about 0.1 parts per million (ppm) to about 5 ppm from the time of manufacture to about 1 month from manufacture when stored at room temperature,

wherein the composition is enclosed in a single-use container having a volume of from about 10 mL to about 100 mL.

26. Claim 4 of the '453 patent reads as follows:

The composition of claim 1, wherein said Aluminum is present in an amount from about 1.0 ppb to about 150 ppb.

27. Claim 22 of the '453 patent reads as follows:

A method of preparing a reduced Aluminum composition for a total parenteral nutrition regimen comprising L-cysteine, the method comprising:

mixing a composition comprising L-cysteine and/or a pharmaceutically acceptable salt thereof and/or hydrate thereof comprising:

Aluminum in an amount from about 1.0 parts per billion (ppb) to about 250 ppb;

L-cystine in an amount from about 0.001 wt % to about 2.0 wt % relative to L-cysteine; and

pyruvic acid in an amount from about 0.001 wt % to about 2.0 wt % relative to L-cysteine;

with a composition comprising one or more amino acids selected from the group consisting of: leucine, isoleucine, lysine, valine, phenylalanine, histidine, threonine, methionine, tryptophan, alanine, arginine, glycine, proline, serine, and tyrosine; and a pharmaceutically acceptable carrier, comprising water, to form a composition for infusion having a volume of about 100 mL to about 1000 mL,

wherein the Aluminum provided in said parenteral nutrition regimen is from about 1-2 to about 4-5 micrograms/kg/day.

28. Exela's ELCYS® product, and its use according to the directions and instructions on the FDA-approved label, is covered by at least claims 1, 4 and 22 of the '453 patent.

C. The Asserted '155 Patent

29. On March 10, 2020, the USPTO issued the '155 patent, entitled "Stable, Highly Pure L-Cysteine Compositions for Injection and Methods of Use," and naming John Maloney, Aruna Koganti, and Phanesh Koneru as inventors. A copy of the '155 patent is attached to this Complaint as Exhibit D.

30. The '155 patent is assigned to Plaintiff Exela.

31. On March 10, 2020, Exela submitted the '155 patent for listing in the Orange Book, which provides notice concerning patents covering FDA-approved drugs.

32. On or about March 11, 2020, the FDA published the '155 patent in the Orange Book.

33. Claim 1 of the '155 patent reads as follows:

> A method of treating a subject having an adverse health condition that is responsive to L-cysteine administration, said method comprising:
> parenterally administering to said subject a parenteral composition comprising a mixture of one or more amino acids, intravenous fluid, and a stable L-cysteine composition, wherein said stable L-cysteine composition contributes to said parenteral composition:
> a therapeutically effective amount of L-cysteine or a pharmaceutically acceptable salt thereof and/or hydrate thereof;
> per Liter of said stable L-cysteine composition, from about 1.0 mcg to about 250 mcg of Aluminum;
> not more than about 2.0 wt% of cystine relative to L-cysteine; and
> not more than about 2.0 wt% of pyruvic acid relative to L-cysteine.

34. Claim 3 of the '155 patent reads as follows:

> The method of claim 1, wherein said stable L-cysteine composition contributes Aluminum in an amount less than 150 mcg/L.

35. Claim 27 of the '155 patent reads as follows:

> A method of treating a subject having an adverse health condition that is responsive to L-cysteine administration, said method comprising:
> parenterally administering to said subject a parenteral composition comprising a mixture comprising a stable L-cysteine composition, wherein said stable L-cysteine composition contributes to said parenteral composition:
> a therapeutically effective amount of L-cysteine or a pharmaceutically acceptable salt thereof and/or hydrate thereof;
> per Liter of said stable L-cysteine composition, not more than about 150 mcg of Aluminum;
> cystine relative to L-cysteine not more than about 2.0 wt%; and
> pyruvic acid relative to L-cysteine not more than about 2.0 wt%.

36. Exela's ELCYS® product, and its use according to the directions and instructions on the FDA-approved label, is covered by at least claims 1, 3 and 27 of the '155 patent.

ACTS GIVING RISE TO THIS ACTION FOR DEFENDANT'S INFRINGEMENT OF THE PATENTS-IN-SUIT

37. On or about February 3, 2020, Plaintiff received a letter, dated January 31, 2020, signed on behalf of Eton by Jeffrey Wolfson of the law firm Haynes Boone ("Eton's Paragraph IV Letter").

38. Eton's Paragraph IV Letter states that Eton had filed Abbreviated New Drug Application ("ANDA") No. 214082 with the FDA seeking approval for Cysteine Hydrochloride Injection, USP, 500 mg/50 mL (50 mg/mL), 10 mL Fill ("Eton's Proposed Generic Cysteine Hydrochloride Product"), which is a generic version of Exela's ELCYS® product.

39. This action is being commenced before the expiration of 45 days from the date Exela received Eton's Paragraph IV Letter, which triggers a stay of FDA approval of Eton's ANDA No. 214082 pursuant to 21 U.S.C § 355(j)(5)(B)(iii).

40. Eton's Paragraph IV Letter states that "[t]he basis of [its] proposed abbreviated new drug application (ANDA) for Cysteine Hydrochloride Injection, USP, 500 mg/10 mL (50 mg/mL), 10 mL Fill, is the reference listed drug (RLD) and Reference Standard (RS), ELCYS® (Cysteine Hydrochloride) Injection, USP, 50 mg/mL, NDA 210660, approved on April 16, 2019, held by Exela Pharma Sciences, LLC, which is listed as the RLD and RS" in the Orange Book.

41. Eton's Paragraph IV Letter also states that ANDA No. 214082 contains any required bioavailability or bioequivalence data and a Paragraph IV certification for the '453 patent.

42. On information and belief, Eton submitted to the FDA ANDA No. 214082 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of

Eton's Proposed Generic Cysteine Hydrochloride Product before the expiration of the '453 patent.

43. Attached to Eton's Paragraph IV Letter is a statement of the factual and legal bases for Eton's position that the '453 patent is invalid and/or will not be infringed by the commercial manufacture, use, or sale of Eton's Proposed Generic Cysteine Hydrochloride Product described in ANDA No. 214082.

44. In particular, Eton's Paragraph IV letter alleges that claims 1-21 of the '453 patent are not infringed and claim 22 of the '453 patent is invalid.

45. Eton's Paragraph IV Letter does not allege invalidity of claims 1-21 of the '453 patent or non-infringement of claim 22 of the '453 patent.

46. Eton's Paragraph IV Letter is not marked confidential.

47. Attached to Eton's Paragraph IV Letter is an Offer of Confidential Access to ANDA No. 214082. The terms of the proposed Offer would not allow Plaintiff to conduct a complete and full investigation of the information contained in the ANDA and of the representations about Eton's Proposed Generic Cysteine Hydrochloride Product that appear in Eton's Paragraph IV Letter. For example, the Offer would not allow in-house counsel for Plaintiff to review the ANDA and only obligates Eton to produce the portions of the ANDA that Eton unilaterally deems "pertinent" to patent infringement rather the producing the entire ANDA. Thus, Plaintiff could not agree to the terms of the original Offer of Confidential Access.

48. On February 13, 2020, counsel for Plaintiff sent a letter to counsel for Eton in an attempt to negotiate the terms of Plaintiff's access to ANDA No. 214082. After counsel for Eton responded, counsel for Plaintiff followed up by providing a redlined version of the Offer of Confidential Access, setting forth terms for access that would be acceptable to Plaintiff. The

parties were not able to reach an agreement regarding access to ANDA No. 214082 prior to the expiry of the time period set forth in 21 U.S.C. § 355(j)(5)(B)(iii). Plaintiff thus makes these allegations based on information and belief, the laws and regulations regarding generic drugs, and Eton's Paragraph IV Letter.

49. Because Eton's Proposed Generic Cysteine Hydrochloride Product has not yet been approved by FDA and is not is yet commercially available, Plaintiff is not aware of any other means for obtaining information about Eton's Proposed Generic Cysteine Hydrochloride Product other than pursuant to an Offer of Confidential Access from Eton. In the absence of additional information, Plaintiff resorts to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and present to the Court evidence that Eton's Proposed Generic Cysteine Hydrochloride Product infringes one or more claims of the '453 and '155 patents.

50. In filing and maintaining ANDA No. 214082, Eton has requested and continues to request FDA's approval to market a generic version of Exela's ELCYS® product throughout the United States, including in Delaware.

51. On information and belief, following FDA approval of ANDA No. 214082, Eton will offer for sale and sell the approved generic version of ELCYS® throughout the United States, including in Delaware.

52. Eton's effort to seek FDA approval to market a generic version of ELCYS® prior to the expiration of the '453 and '155 patents constitutes an act of infringement pursuant to 35 U.S.C. § 271(e)(2). It also creates a justiciable controversy between the parties with respect to the subject matter of ANDA No. 214082, the '155 patent, and the '453 patent, as further evidenced by Eton's Paragraph IV Letter.

53. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product will be sold and distributed with labeling that contains substantially the same instructions for use as those in the label for Exela's ELCYS® product, including instructions that are substantially the same as those described above in paragraphs 14-20.

54. For example, on information and belief, the labeling for Eton's Proposed Generic Cysteine Hydrochloride Product, like the labeling for ELCYS®, will instruct healthcare providers that the product is indicated for use as an additive to amino acid solutions to meet nutritional requirements of newborn infants requiring total parenteral nutrition and adult and pediatric patients who may have impaired enzymatic processes and require TPN.

55. On information and belief, based on that instruction, which will appear in the indications and usage section of the label for Eton's Proposed Generic Cysteine Hydrochloride Product, the product will be used to treat patients who have adverse health conditions that are responsive to L-cysteine administration.

56. Eton's Proposed Generic Cysteine Hydrochloride Product contains L-cysteine in an amount from 10-100 mg/mL. Specifically, Eton's Paragraph IV Letter states that its Proposed Generic Cysteine Hydrochloride Product is an injection containing 500 mg/10mL (50 mg/mL) cysteine hydrochloride, USP in a 10 mL single-dose vial. On information and belief, like ELCYS®, Eton's Proposed Generic Cysteine Hydrochloride Product comprises water as the carrier for L-cysteine.

57. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product is stable and will not be approved by FDA if it is not stable.

58. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product contains no more than 145 mcg/L of aluminum, per FDA's requirements, and will state that on its labeling.

59. On information and belief, and especially in view of the FDA-approved product specifications for ELCYS®, Eton's Proposed Generic Cysteine Hydrochloride Product contains no more than 2.0% total impurities. On information and belief, because FDA had already approved ELCYS® with a specification limiting total impurities to no more than 2.0% before Eton filed ANDA No. 214082, FDA will not approve another cysteine hydrochloride product that permits impurities at a level greater than 2.0%.

60. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product therefore contains less than 2.0% of the impurities cystine and pyruvic acid relative to L-cysteine, and thus, on information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product contains from about 0.001 wt % to about 2.0 wt% cystine (or L-cystine) relative to L-cysteine and from about 0.001 wt % to about 2.0 wt % pyruvic acid relative to L-cysteine.

61. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product contains dissolved oxygen present in the carrier in an amount from about 0.1 ppm to about 5 ppm from the time of manufacture to about 1 month from manufacture when stored at room temperature. Indeed, Eton's Paragraph IV Letter makes no claim that its Proposed Generic Cysteine Hydrochloride Product does not have dissolved oxygen levels in this range.

62. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product contains headspace oxygen that is from about 0.5% v/v to 4.0% v/v from the time of manufacture to about 1 month from manufacture when stored at room temperature. As disclosed in the '453 patent in Example 5, even when a robust process is followed to reduce headspace

oxygen—for example, a high-speed filler capable of using vacuum and gas overlay in alternate pulses—the headspace oxygen in at least some vials so treated is present at about 0.5% v/v upon manufacture and from about 0.5% v/v to over 1.5% v/v (but less than 4.0% v/v) at about 1 month from the time of manufacture when stored at room temperature. [Ex. C at 48:15-49:67; 28:48-58.] In addition, as the '453 patent discloses in Examples 4 and 5, when headspace oxygen is reduced by means of a lyophilization process, the headspace oxygen in vials containing a cysteine solution is present, on average, from about 1.9% v/v to about 2.3% v/v upon manufacture and about 0.9% v/v to about 2.8% v/v at about 1 month after manufacture. [Ex. C at 44:1-49:67, 28:48-58.] Because Eton's Proposed Generic Cysteine Hydrochloride Product contains, on information and belief, similar components and similar amounts of headspace oxygen and dissolved oxygen at the time of manufacture as the cysteine solutions of Example 5 of the '453 patent, on information and belief Eton's Proposed Generic Cysteine Hydrochloride Product will exhibit similar trends in headspace oxygen from the time of manufacture to about 1 month from manufacture as the cysteine solutions of Example 5, and thus will contain headspace oxygen from about 0.5% v/v to 4.0% v/v from the time of manufacture to about 1 month after manufacture when stored at room temperature.

63. On information and belief, the labeling for the Eton's Proposed Generic Cysteine Hydrochloride Product, like the label for ELCYS®, will instruct healthcare providers that, prior to administration, the product must be diluted and used as an admixture in parenteral nutrition solutions. On information and belief, like the label for ELCYS®, the label for Eton's Proposed Generic Cysteine Hydrochloride Product will also provide instructions as to how to prepare that admixture for use in a TPN solution.

64. On information and belief, the label for Eton's Proposed Generic Cysteine Hydrochloride Product will provide the same instructions as the label for ELCYS® for admixing the product with one or more amino acid, and following those instructions on the label produces a composition comprising L-cysteine along with one or more amino acids (including leucine, isoleucine, lysine, valine, phenylalanine, histidine, threonine, methionine, tryptophan, alanine, arginine, glycine, proline, serine, or tyrosine) and intravenous fluid or water.

65. On information and belief, the label for Eton's Proposed Generic Cysteine Hydrochloride Product will contain the same warning as the label for ELCYS®, described above in Paragraph 20, about patients receiving greater than 4 to 5 mcg/kg/day of parenteral aluminum. On information and belief, following the instructions on the label for Eton's Proposed Generic Cysteine Hydrochloride Product results in a parenteral nutrition regimen with aluminum present in an amount from 1-2 to 4-5 micrograms/kg/day.

66. On information and belief, a composition prepared according to the admixture instructions on the label for Eton's Proposed Generic Cysteine Hydrochloride Product will be used for infusion in a TPN regimen and has a volume of about 100 mL to about 1000 mL.

67. On information and belief, the labeling for the Eton's Proposed Generic Cysteine Hydrochloride Product, like the label for ELCYS®, will instruct healthcare providers that the dosage of the final TPN solution must be based on the concentrations of all the components in the solution and the recommended nutritional requirements. On information and belief, when used as directed on the label, Eton's Proposed Generic Cysteine Hydrochloride Product will be dosed to provide a therapeutically effective amount of L-cysteine to patients.

68. On information and belief, the composition of Eton's Proposed Generic Cysteine Hydrochloride Product meets all the limitations of at least claims 1 and 4 of the '453 patent, either literally or under the doctrine of equivalents.

69. On information and belief, healthcare providers will admix Eton's Proposed Generic Cysteine Hydrochloride Product according to the instructions on Eton's label and administer those compositions to patients who require TPN.

70. On information and belief, when healthcare providers admix Eton's Proposed Generic Cysteine Hydrochloride Product according to the instructions on Eton's label to prepare compositions for a TPN regimen and/or administer those compositions to patients who require TPN, they will satisfy all the limitations of at least claim 22 of the '453 patent and claims 1, 3 and 27 of the '155 patent, either literally or under the doctrine of equivalents.

71. Accordingly, on information and belief, healthcare providers that follow the instructions on the labeling for Eton's Proposed Generic Cysteine Hydrochloride Product will directly infringe at least some claims of the '453 and '155 patents.

COUNT I

(Infringement of the '453 Patent Under 35 U.S.C. § 271(e)(2))

72. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

73. Eton submitted ANDA No. 214082 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product throughout the United States. By submitting the application, Eton has committed an act of infringement of the '453 patent under 35 U.S.C. § 271(e)(2)(A).

74. The commercial manufacture, importation, use, sale, or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product will constitute an act of direct infringement of the '453 patent, either literally or under the doctrine of equivalents.

75. On information and belief, Eton became aware of the '453 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using ELCYS®, and no later than when it submitted a paragraph IV certification to FDA regarding ANDA No. 214082, in which it identified the '453 patent as a patent covering the approved product ELCYS®.

76. On information and belief, Eton knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of Eton's Proposed Generic Cysteine Hydrochloride Product, with its labeling, will actively induce the direct infringement of the '453 patent.

77. On information and belief, Eton knew or should have known that Eton's Proposed Generic Cysteine Hydrochloride Product will be especially made or especially adapted for use in an infringement of the '453 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidence by, for example, the contents of its proposed labeling. And, on information and belief, Eton knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of Eton's Proposed Generic Cysteine Hydrochloride Product will actively contribute to the direct infringement of the '453 patent.

78. Unless and until Eton is enjoined from infringing the '453 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

79. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Eton's ANDA No. 214082 be a date that is not earlier than the expiration date of the '453 patent.

COUNT II

(Declaratory Judgment of Infringement of the '453 Patent Under 35 U.S.C. § 271(a))

80. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

81. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

82. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

83. On information and belief, Eton will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Eton's Proposed Generic Cysteine Hydrochloride Product immediately and imminently upon FDA approval of ANDA No. 214082.

84. Eton's actions, including but not limited to, the development of Eton's Proposed Generic Cysteine Hydrochloride Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Eton has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, and/or import Eton's Proposed Generic Cysteine Hydrochloride Product.

85. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product practices all limitations of at least claims 1 and 4 of the '453 patent, either literally or under the doctrine of equivalents, as detailed above, and thus the manufacture, importation, use, sale, and/or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product will constitute an act of infringement of the '453 patent.

86. The commercial manufacture, importation, use, sale, or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product in violation of Plaintiff's patent rights will cause harm to Plaintiff, for which damages are inadequate.

87. Plaintiff is entitled to a declaratory judgment that the future manufacture, use, offer for sale, sale and/or importation of Eton's Proposed Generic Cysteine Hydrochloride Product before patent expiration will constitute direct infringement of at least claims 1 and 4 of the '453 patent under 35 U.S.C. § 271(a).

88. Unless and until Eton is enjoined from infringing the '453 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

COUNT III

(Declaratory Judgment of Infringement of the '453 Patent Under 35 U.S.C. § 271(b))

89. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

90. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

91. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

92. Eton has actual knowledge of the '453 patent.

93. On information and belief, Eton became aware of the '453 patent no later than when it was when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using ELCYS®, and no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 214082, in which it identified the '453 patent as one of the patents covering ELCYS®.

94. On information and belief, Eton will engage in the commercial manufacture, use, offer for sale, sale, importation or other promotion and/or distribution of Eton's Proposed Generic Cysteine Hydrochloride Product immediately and imminently upon FDA approval of ANDA No. 214082.

95. Eton's actions, including but not limited to, the development of Eton's Proposed Generic Cysteine Hydrochloride Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Eton has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute Eton's Proposed Generic Cysteine Hydrochloride Product.

96. On information and belief, Eton will include within the packaging of its Proposed Generic Cysteine Hydrochloride Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 22 of the '453 patent.

97. On information and belief, healthcare providers preparing a total parenteral nutrition regimen using Eton's Proposed Generic Cysteine Hydrochloride Product within the United States according to the instructions in the product's labeling will directly infringe at least claim 22 of the '453 patent, either literally or under the doctrine of equivalents.

98. On information and belief, Eton possesses specific intent to encourage direct infringement of at least claim 22 of the '453 patent, including because Eton's labeling for its Proposed Generic Cysteine Hydrochloride Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because ELCYS® and Eton's Proposed Generic Cysteine Hydrochloride Product have no

substantial non-infringing uses, Eton intends for the use of its generic version of ELCYS® to directly infringe at least claim 22 the '453 patent.

99. On information and belief, upon awareness of the '453 patent, Eton either actually knew of the potential for infringement of at least claim 22 of the '453 patent, or was willfully blind as to the potential for that infringement at least because Eton provides instructions for infringement of at least claim 22 of the '453 patent in its proposed product labeling.

100. The commercial making, using, offering to sell, selling, importing, or otherwise promoting and/or distributing of Eton's Proposed Generic Cysteine Hydrochloride Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 22 of the '453 patent.

101. Eton's Paragraph IV letter makes no allegations of non-infringement for claim 22 of the '453 patent.

102. The commercial making, using, offering to sell, selling, importing, or otherwise promoting and/or distributing of Eton's Proposed Generic Cysteine Hydrochloride Product in violation of Plaintiff's patent rights will cause harm to Plaintiff, for which damages are inadequate.

103. Plaintiff is entitled to a declaratory judgment that the future making, using, offering to sell, selling, importing, or otherwise promoting and/or distributing of Eton's Proposed Generic Cysteine Hydrochloride Product before patent expiration will constitute active inducement of infringement of at least claim 22 of the '453 patent under 35 U.S.C. § 271(b).

104. Unless and until Eton is enjoined from infringing the '453 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

COUNT IV

(Declaratory Judgment of Infringement of the '453 Patent Under 35 U.S.C. § 271(c))

105. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

106. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

107. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

108. Eton has actual knowledge of the '453 patent.

109. On information and belief, Eton became aware of the '453 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering ELCYS®, and no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 214082, in which it identified the '453 patent as one of the patents covering ELCYS®.

110. On information and belief, Eton will engage in the commercial manufacture, use, offer for sale, sale, importation and/or other distribution of Eton's Proposed Generic Cysteine Hydrochloride Product immediately and imminently upon FDA approval of ANDA No. 214082.

111. Eton's actions, including but not limited to, the development of Eton's Proposed Generic Cysteine Hydrochloride Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Eton has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to sell, offer to sell, import and/or otherwise distribute Eton's Proposed Generic Cysteine Hydrochloride Product.

112. On information and belief, Eton will include within the packaging of its Proposed Generic Cysteine Hydrochloride Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 22 of the '453 patent.

113. On information and belief, healthcare providers preparing a total parenteral nutrition regimen using Eton's Proposed Generic Cysteine Hydrochloride Product within the United States according to the instructions in the product's labeling will directly infringe at least claim 22 of the '453 patent, either literally or under the doctrine of equivalents.

114. On information and belief, Eton knows that its Proposed Generic Cysteine Hydrochloride Product is a material part of the method of at least claim 22 of the '453 patent, including as evidenced in the contents of its proposed label. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product was especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 22 of the '453 patent, as evidenced in the contents of its proposed labeling. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for cysteine hydrochloride injections other than treating patients pursuant to FDA's approval for such products.

115. Thus, on information and belief, Eton will contribute to the infringement of at least claim 22 of the '453 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing Eton's Proposed Generic Cysteine Hydrochloride Product, which is a material for use in practicing the method of at least claim 22 of the '453 patent.

116. Eton's Paragraph IV Letter makes no allegations of non-infringement for claim 22 of the '453 patent.

117. The commercial offering to sell, selling, importing and/or other distribution of Eton's Proposed Generic Cysteine Hydrochloride Product for use in practicing the patented method in violation of Plaintiff's patent rights will cause harm to Plaintiff, for which damages are inadequate.

118. Plaintiff is entitled to a declaratory judgment that the future offer for sale, sale, importation and/or other distribution of Eton's Proposed Generic Cysteine Hydrochloride Product before patent expiration will constitute contributory infringement of the claims of the '453 patent under 35 U.S.C. § 271(c).

119. Unless and until Eton is enjoined from infringing the '453 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

COUNT V

(Infringement of the '155 Patent Under 35 U.S.C. § 271(e)(2))

120. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

121. Eton submitted ANDA No. 214082 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product throughout the United States. By submitting the application, Eton has committed an act of infringement of the '155 patent under 35 U.S.C. § 271(e)(2)(A).

122. The use of Eton's Proposed Generic Cysteine Hydrochloride Product according to the instructions in the product's label will constitute an act of direct infringement of the '155 patent, either literally or under the doctrine of equivalents.

123. On information and belief, Eton monitors the status of patent applications filed by Exela that relate to L-Cysteine drug products and the contents of the Orange Book for the RLDs serving as the basis for its ANDA submissions, including ELCYS®.

124. On information and belief, Eton became aware of the ’155 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using ELCYS®.

125. On information and belief, Eton knew or should have known that its commercial making, offering to sell, selling, importing, or otherwise promoting and/or distributing of Eton’s Proposed Generic Cysteine Hydrochloride Product, with its labeling, will actively induce the direct infringement of the ’155 patent.

126. On information and belief, Eton knew or should have known that Eton’s Proposed Generic Cysteine Hydrochloride Product will be especially made or especially adapted for use in an infringement of the ’155 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on information and belief, Eton knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of Eton’s Proposed Generic Cysteine Hydrochloride Product with its labeling will actively contribute to the direct infringement of the ’155 patent.

127. Unless and until Eton is enjoined from infringing the ’155 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

128. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Eton’s ANDA No. 214082 be a date that is not earlier than the expiration date of the ’155 patent.

COUNT VI

(Declaratory Judgment of Infringement of the ’155 Patent Under 35 U.S.C. § 271(b))

129. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

130. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

131. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

132. Eton has actual knowledge of the '155 patent.

133. On information and belief, Eton monitors the status of patent applications filed by Exela that relate to L-cysteine drug products and the contents of the Orange Book for the RLDs serving as the basis for its ANDA submissions, including ELCYS®.

134. On information and belief, Eton became aware of the '155 patent no later than when it when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using ELCYS®.

135. On information and belief, Eton will engage in the commercial manufacture, use, offer for sale, sale, importation or other promotion and/or distribution of Eton's Proposed Generic Cysteine Hydrochloride Product immediately and imminently upon FDA approval of ANDA No. 214082.

136. Eton's actions, including but not limited to, the development of Eton's Proposed Generic Cysteine Hydrochloride Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Eton has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute Eton's Proposed Generic Cysteine Hydrochloride Product.

137. On information and belief, Eton will include within the packaging of its Proposed Generic Cysteine Hydrochloride Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claims 1, 3 and 27 of the ’155 patent.

138. On information and belief, healthcare providers administering a parenteral nutrition regimen including Eton’s Proposed Generic Cysteine Hydrochloride Product within the United States according to the instructions in the product’s labeling will directly infringe at least claim 1, 3 and 27 of the ’155 patent, either literally or under the doctrine of equivalents.

139. On information and belief, Eton possesses specific intent to encourage direct infringement of at least claims 1, 3 and 27 of the ’155 patent, including because Eton’s labeling for its Proposed Generic Cysteine Hydrochloride Product instructs users to perform the patented methods, providing evidence of an affirmative intent to induce infringement. Furthermore, because ELCYS® and Eton’s Proposed Generic Cysteine Hydrochloride Product have no substantial non-infringing uses, Eton intends for the administration of its generic version of ELCYS® to directly infringe at least claims 1, 3 and 27 of the ’155 patent.

140. On information and belief, upon awareness of the ’155 patent, Eton either actually knew of the potential for infringement of at least claims 1, 3 and 27 of the ’155 patent, or was willfully blind as to the potential for that infringement at least because Eton provides instructions for infringement of at least claims 1, 3 and 27 of the ’155 patent in its proposed product labeling.

141. The commercial making, using, offering to sell, importing, or otherwise promoting and/or distributing of Eton’s Proposed Generic Cysteine Hydrochloride Product, with its labeling, will constitute an act of active inducement of infringement of at least claims 1, 3 and 27 of the ’155 patent.

142. The commercial making, using, offering to sell, importing, or otherwise promoting and/or distributing of Eton's Proposed Generic Cysteine Hydrochloride Product in violation of Plaintiff's patent rights will cause harm to Plaintiff, for which damages are inadequate.

143. Plaintiff is entitled to a declaratory judgment that the future making, using, offering to sell, importing, or otherwise promoting and/or distributing of Eton's Proposed Generic Cysteine Hydrochloride Product before patent expiration will constitute active inducement of infringement of at least claims 1, 3 and 27 of the '155 patent under 35 U.S.C. § 271(b).

144. Unless and until Eton is enjoined from infringing the '155 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

COUNT VII

(Declaratory Judgment of Infringement of the '155 Patent Under 35 U.S.C. § 271(c))

145. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

146. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

147. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

148. Eton has actual knowledge of the '155 patent.

149. On information and belief, Eton monitors the status of patent applications filed by Exela that relate to L-cysteine drug products and the contents of the Orange Book for the RLDs serving as the basis for its ANDA submissions, including ELCYS®.

150. On information and belief, Eton became aware of the '155 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using ELCYS®.

151. On information and belief, Eton will engage in the commercial offer for sale, sale, importation and/or other distribution of Eton's Proposed Generic Cysteine Hydrochloride Product immediately and imminently upon FDA approval of ANDA No. 214082.

152. Eton's actions, including but not limited to, the development of Eton's Proposed Generic Cysteine Hydrochloride Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Eton has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to sell, offer to sell, import and/or otherwise distribute Eton's Proposed Generic Cysteine Hydrochloride Product.

153. On information and belief, Eton will include within the packaging of its Proposed Generic Cysteine Hydrochloride Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claims 1, 3 and 27 of the '155 patent.

154. On information and belief, healthcare providers administering a parenteral nutrition regimen including Eton's Proposed Generic Cysteine Hydrochloride Product within the United States according to the instructions in the product's labeling will directly infringe at least claims 1, 3 and 27 of the '155 patent, either literally or under the doctrine of equivalents.

155. On information and belief, Eton knows that its Proposed Generic Cysteine Hydrochloride Product is a material part of the method of at least claims 1, 3 and 27 of the '155 patent, including as evidenced in the contents of its proposed label. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product was especially made or especially

adapted for use by a healthcare provider in a manner that will directly infringe at least claims 1, 3 and 27 of the '155 patent, as evidenced by the contents of its proposed labeling. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for cysteine hydrochloride injections other than treating patients pursuant to FDA's approval for such products.

156. Thus, on information and belief, Eton will contribute to the infringement of the claims of the '155 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing Eton's Proposed Generic Cysteine Hydrochloride Product, which is a material for use in practicing the method of at least claims 1, 3 and 27 of the '155 patent.

157. The commercial offering to sell, selling, importing and/or other distribution of Eton's Proposed Generic Cysteine Hydrochloride Product for use in practicing the patented methods in violation of Plaintiff's patent rights will cause harm to Plaintiff, for which damages are inadequate.

158. Plaintiff is entitled to a declaratory judgment that the future offer for sale, sale, importation and/or other distribution of Eton's Proposed Generic Cysteine Hydrochloride Product before patent expiration will constitute contributory infringement of at least claims 1, 3 and 27 of the '155 patent under 35 U.S.C. § 271(c).

159. Unless and until Eton is enjoined from infringing the '155 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for the following relief:

A. That judgment be issued that Defendant has infringed the ’453 and ’155 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA 214082 under section 505(j) of the Federal Food, Drug and Cosmetic Act, and that the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Defendant’s Proposed Generic Cysteine Hydrochloride Product will constitute an act of infringement of the ’453 and ’155 patents;

B. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Defendant’s ANDA No. 214082 shall be a date which is not earlier than the expiration dates of the ’453 and ’155 patents, as extended by any applicable period of exclusivity;

C. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendant, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by, or drug product whose use is covered by, the ’453 or ’155 patent;

D. That a declaration be issued under 28 U.S.C. § 2201 that the manufacture, use, offer for sale, sale and/or importation of Defendant’s Proposed Generic Cysteine Hydrochloride Product before expiration of the ’453 and ’155 patents does and will infringe the ’453 and ’155 patents.

E. That an order be issued preliminarily and permanently enjoining Defendant and its affiliates, subsidiaries, officers, agents, employees, attorneys, and all persons in active concert

or participation with any of them, or acting on their behalf, from infringing the '453 and '155 patents;

F. If Defendant engages in the commercial manufacture, use, offer to sell, sale, or importation of Defendant's Proposed Generic Cysteine Hydrochloride Product disclosed in ANDA No. 214082 prior to the expiration of the '453 and '155 patents, as extended by any applicable period of exclusivity, judgment awarding Plaintiff damages resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found and/or assessed together with prejudgment and post-judgment interest and costs under 35 U.S.C. § 284;

G. That this case be declared an exceptional case under 35 U.S.C. § 285, and that Plaintiff be awarded reasonable attorneys' fees and costs;

H. That an accounting be performed of Defendant's infringing activities not presented at trial and an award by the Court of additional damages for any such infringing sales; and

I. That this Court award such other and further relief as it may deem just and proper.

JURY TRIAL DEMANDED

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff hereby demands a trial by jury of all issues so triable. Specifically, Plaintiff demands a jury trial in the event that there is a launch at risk and damages are in issue.

Dated: March 16, 2020

By: /s/ *Robert M. Oakes*

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